

REMARKS

Claims 1, 3 – 14, 16 – 22, and 24 - 29 are currently pending. Claims 24 – 29 are new. Claim 1 and claim 24 are the pending independent claims. In the Office Action, Claims 1 and 3 – 22 were rejected under Section 112, first paragraph as allegedly failing to comply with the written description requirement. In addition, Claims 3 – 8 and 13 were rejected under Section 112, second paragraph as allegedly indefinite.

On the merits, Claims 1, 3 – 14, and 16 – 22 were rejected under Section 102 (b) as allegedly anticipated by U.S. Patent No. 4,680,262 to Bochner et al. (“Bochner”). In addition, Claims 1, 6 – 8, 14, and 16 – 21 were rejected under Section 102 (b) as allegedly anticipated by U.S. Patent No. 5,710,027 to Hauptmann et al. (“Hauptmann”). Finally, Claims 1, 3, 6 – 9, 14, and 16 – 21 were rejected under Section 102 (b) as allegedly anticipated by the Hart et al. publication (“Hart”).

In response to the final Office Action mailed on August 27, 2008, Applicants, pursuant to 37 CFR § 1.114, request continued examination by filing the submission of amendments to the claims (above), new claims, and filing the appropriate fee under 37 CFR § 1.17(e). No new matter has been added by the amendments and/or new claims. Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the following remarks.

The Section 112 Rejections.

The Examiner’s contends that Claims 1 and 3-22 encompass maintaining the fermentation medium, apart from the host cell, under defined conditions of temperature and pH prior to extraction of the polypeptide. The Examiner argues that this is not supported by the specification because, in his view, the specification only discloses maintaining the fermentation medium, together with the host cell, under defined conditions of temperature and pH prior to extraction of the polypeptide.

Without acknowledging the correctness of the Examiner’s position, Applicants have amended Claim 1 to specify that both the fermentation medium and the host cell in the medium are maintained under defined conditions of temperature and pH prior to extraction of the polypeptide. It is submitted that this amendment overcomes any possible § 112 difficulties in Claim 1 and that, as a result, the written description rejection should be withdrawn.

In addition, the Examiner contends that Claims 3 – 8 and 13 lack antecedent basis for the limitations “the further processing of the fermentation medium” and that Claims 6-8 lack antecedent basis for the limitations “the interruption of the further processing of the fermentation medium”. The Examiner argues that these claim limitations lack sufficient antecedent basis is because, in his view, Claim 1 refers to the “further processing of the host cell in the fermentation medium” rather than the “further processing of the fermentation medium” itself.

In response, the Applicants have herein amended the referenced Claims to more closely align with the language of Claim 1. Claims 3 – 5 and 13 now recite “the further processing of the host cell in the fermentation medium” and Claims 6 – 8 now call for “the interruption of the further processing of the host cell in the fermentation medium.” It is submitted that these amendments overcome any possible indefiniteness or antecedent basis problems and that, as a result, all rejections based thereon should be withdrawn.

The Prior Art Rejections.

Turning now to the rejections on art, Applicants note that neither Bochner, Hauptmann, nor Hart is cited against the subject matter of Claim 15. In the previous Office Action, the Kwon reference was cited against Claim 15, but this rejection was withdrawn. Thus, it appears the subject matter of Claim 15 is deemed to patentably distinguishes over the art of record.

In view of this, Claim 1 has been amended to incorporate the limitations of Claim 15. As a result, all prior art rejections of Claim 1 should be withdrawn.

It is also noted these amendments are made solely in the interest of expeditiously advancing the current case to allowance. Applicants expressly reserve their right to prosecute additional/other claims of similar or different scope in one or more continuation or other applications.

In view of the Examiner’s stance with regard to Claim 15, Applicants have also added new Claims 24 – 29. Claim 24 is very similar to claim 1, as amended, except that in claim 24 the fermentation medium is concentrated by centrifugation or micro filtration prior to or subsequent to the interruption step b). The breadth of claim 24 is fully supported by the specification as originally filed. See, e.g., PCT/EP2004/009321, page 10, last sentence of paragraph 2 (“The concentration of the fermentation harvest broth may be done before or after

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the interruption step . . ."). As an additional note, persons having ordinary skill in the art will no doubt appreciate that if some of the fermentation medium concentration step occurs prior to interruption, some of the concentration step may also occur during interruption and that any such portions of the concentration step would necessarily be covered by both Claim 1 and by Claim 24.

In view of the foregoing, Applicants urge favorable reconsideration and allowance of Claims 1, 3 – 14, 16 – 22, and 24 - 29.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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